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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,753	02/06/2002	Abraham Amir	02/23230	4762
7590 12/15/2003			EXAMINER	
G.E. EHRLICH (1995) LTD. c/o ANTHONY CASTORINA SUITE 207 2001 JEFFERSON DAVIS HIGHWAY ARLINGTON, VA 22202			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 12/15/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/066,753		AMIR ET AL.	
	Examiner		Art Unit	
	Susan Coe		1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2003 has been entered.
2. Claim 2 has been cancelled.
3. Claims 1 and 3-14 are pending.
4. In Paper No. 5, dated November 25, 2002, applicant elected of Group I, claims 1-8, without traverse.
5. Claims 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.
6. Claims 1 and 3-8 are examined on the merits.
7. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

8. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al. (Facial Plastic Surgery (1995), vol. 11, no. 4, pp. 278-283) for the reasons set forth in the final rejection of May 29, 2003.

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All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. As in the response filed March 17, 2003, applicant argues that the reference does not teach the claimed invention because the reference does not teach using "template-free" cells. However, applicant's claims only require that the cartilage producing cells are in suspension. As discussed in the final rejection, Merriam-Webster's Collegiate Dictionary (10th edition, 1997) defines a "suspension" as "the state of a substance when its particles are mixed with but undissolved in a fluid or solid" and "a system consisting of a solid dispersed in a solid... (see page 1187)." Since the reference teaches that the chondrocytes are seeded into the mesh template and then incubated to allow the cells to grow and adhere to the template (see paragraph spanning pages 280 and 281), the reference is considered to teach a suspension of chondrocytes in that the cells are mixed with a solid.

In addition, the reference is considered to meet the new limitation of "cultured isolated" cells because the reference isolates chondrocytes and cultures the isolated chondrocytes (see page 280 and 281, "Chondrocyte Isolation" and "Tissue Culture").

9. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (Plastic and Reconstructive Surgery (1994), vol. 94, no. 2, pp. 233-237) for the reasons set forth in the final rejection of May 29, 2003.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues against Kim for the same reasons in the traversal of the rejection over Park. Since the teachings of Kim are very similar to Park, the reference is still considered to anticipate the claims for the reasons stated above.

Claim Rejections - 35 USC § 103

10. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. for the reasons set forth in the final rejection of May 29, 2003.

Applicant has not specifically addressed this rejection in the response. Therefore, this rejection is considered valid for the reasons discussed above and in the previous Office action.

11. Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. for the reasons set forth in the previous Office action.

Applicant has not specifically addressed this rejection in the response. Therefore, this rejection is considered valid for the reasons discussed above and in the previous Office action.

12. Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,469,676 in view of Atala et al. (J. Urol. (1993), vol. 150, pp. 745-747).

US '676 teaches a method of treating wrinkles by injecting cartilage cells into the wrinkle (see claims). However, US '676 does not teach using isolated cartilage producing cells, i.e. chondrocytes, to treat wrinkles. Atala teaches that isolated chondrocytes can be administered via subcutaneous injection for use in plastic and reconstructive surgery (see page 747, last paragraph). Atala also teaches that the purpose of injecting the chondrocytes is to produce cartilage at the injection site. The function of US '676 is also to introduce cartilage into the treatment site. Thus, Atala shows that it was known in the art that isolated chondrocytes can be used for the same purpose as the cartilage of US '676. Based on this teaching by Atala, a person of ordinary skill in the art would reasonably expect that isolated chondrocytes could be successfully used in place of the cartilage cells in the method taught by US '676. Therefore,

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based on this reasonable expectation of success, an artisan of ordinary skill would have been motivated to treat wrinkles by subcutaneously injecting chondrocytes into the site of the wrinkle.

Atala teaches isolating the chondrocytes from a calf and injecting the chondrocytes into a mouse. Thus, the reference does not specifically teach using chondrocytes harvested from the subject, a syngeneic source, or an allogeneic source. However, based on the teaching of Atala of using chondrocytes isolated from a different species than the subject, a person of ordinary skill in the art would have a reasonable expectation that using chondrocytes harvested from the subject, a syngeneic source, or an allogeneic source would be successful. If cells from a xenogeneic source do not produce adverse effects, it is reasonable to expect that cells from the subject, a syngeneic source or an allogeneic source would also not produce adverse effects while still imparting the same benefits to the skin. Therefore, a person of ordinary skill in the art would be motivated to use chondrocyte cells from the subject, a syngeneic source or an allogeneic source in the skin treatment method taught by the combination of Atala and US '676.

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Susan Coe, Examiner
December 9, 2003